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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,664	10/10/2002	Guy Rouleau	1619.0110000/SRL/KYP	9379
26111	7590	09/19/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WANG, CHANG YU	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 09/19/2005

Please find below and/or attached ~~an~~ Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,664

Applicant(s)

ROULEAU ET AL.

Examiner

Chang-Yu Wang

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 14, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,11,12,14 and 16-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,5,6,11,12,14 and 16-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, and 16-21, drawn to the first technical feature a method for the diagnosis of a disease associated with protein accumulation in intranuclear inclusion in a cell of a patient as taught by prior art references.

Group II, claim(s) 5, 6, 11, 14, and 22-34, drawn to the second technical feature a method for the screening of agents which can modulate polyamino acid stretch-containing protein expression, accumulation and toxicity.

Group III, claim(s) 12, drawn to the third technical feature a method to trigger toxicity in a cell comprising an increased expression of an alanine polymer stretch in a protein.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The 1st claimed invention is drawn to a method for the diagnosis of a disease associated with protein accumulation in intranuclear inclusion in a cell of a patient which is anticipated by prior art references. As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Caspar et al. "CAG tract of MJD-1 may be prone to frameshifts causing polyalanine accumulation." (Hum. Mol. Genet. 2000. 9:1957-66).

Casper et al. teach alanine polymers deposit in cells from MJD patients forming intranuclear inclusions are transcriptional and translational frameshifts and may contribute to nuclear toxicity, which meet the limitation of claim 1. Therefore, claim 1 is anticipated by Casper et al..

3. Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions do not contribute a special technical feature when view over the prior art, they do not have a single inventive concept and so lack unity of invention.

4. Furthermore, in addition to the election of one of the above III groups, further restriction is required under PCT Rule 13.1 to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

A. If Group I is elected then a single designated type of molecule selected from a ligand or a nucleic acid sequence is required to be elected to which the search will be limited.

5. A ligand and a nucleic acid sequence are directed to different products, thus, restriction is deemed to be proper. A ligand and nucleic acid sequence constitute patentably distinct inventions for the following reasons. A ligand can be a protein or any chemical compound, which has different structural features and functions compared to those of nucleic acids. For example, a Nucleic acid sequence can be used as a probe for hybridization to detect RNA/DNA messages whereas a ligand can bind and mediate other molecules for different functions or be used as a therapeutical agent. Therefore, a ligand and a nucleic acid sequence have no common technical feature.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-III. If Group I is elected, a single designated type of molecule selected from group A as set forth above to which the claims will be restricted, even though the requirement is traversed. . Applicant is advised that neither I-III nor the single designated type of molecule is species election requirements; rather each of Groups I-III and the designated type of molecule are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

Species Election

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

i. Species of modulating condition are as follows:

- A) polyamino acid stretch-containing protein expression
- B) accumulation of polyamino acid stretch-containing proteins in intranuclear inclusion
- C) toxicity of polyamino acid stretch-containnig proteins to cells

ii. Species of cell type are as follows:

- A) A lymphoblast cell from a Machado-Joseph disease (MJD) patient.
- B) A pontine neuron of MJD brain
- C) An in vivo cell culture model of a neurological disease associated with polyamino acid stretch-containing protein
- D) A cell from an oculopharyngeal muscular dystrophy (OPMD) patient

iii. Species of CAG repeat are as follows:

- A) A CAG repeat
- B) An uninterrupted CAG tract.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The claims are deemed to correspond to the species listed above in the following manner:

If Groups II is elected, Applicant is required to elect a specific modulating condition, cell type, and CAG repeat selected from the group recited in claims 6, 11, 14, and 26-31.

The following claim(s) are generic: claim 5.

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

12. The technical features of these species are distinct because each specific species differs with respect to its potential molecular mechanisms contributed to protein expression, accumulation and toxicity. In addition, the etiology and pathology are very different among different disorders, such as MJD or OPMD. Therefore, the cells derived

from different sources, consequently, the outcomes responsive to different agents are distinct. Further, the different numbers of CAG repeat essentially contribute to different outcomes of pathological conditions. Therefore, each species is patentably distinct.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-III. If Group I is elected, a single designated type of molecule from group A is required to be designated. If Group II is elected, a single species for modulating condition, cell type and CAG repeat as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

16. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
September 8, 2005


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER